

### REMARKS

Claims 1-2, 6-7, 9-11, 13-16, 22, 24-27, 28-29, 30, 33-34, 35, 36 and 38 are pending. Claims 28, 29, and 35 are withdrawn and all other claims were rejected.

On September 22, 2009, this attorney conducted a phone interview with three persons from the USPTO: Examiner Webb, Supervisor Krass and, from assignee Natreon, Dr. Sanyasi Kalidindi and Dr. Ratan Chaudhuri in attendance. Agreement was reached that the obviousness rejection, based on the Janjua reference, did not provide a prima facie showing that chromium is complexed to phenolic antioxidant *in situ* in *emblica officinalis*. This argument, in its entirety is presented below, along with response to the other rejections.

#### 35 USC § 102

Claims 1-2, 9-11, 13-16, 22, 24-25, 27, 30, 33, 34, 36 and 38 were rejected under 35 USC § 102(b) as being anticipated by Rowland (U.S. Patent No. 5,405,613), as evidenced by Ghosal (U.S. Patent No. 6,440,436), Janjua (Hamdard Medicus 1991) and Ghosal (U.S. Patent No. 6,124,268). Applicant traverses the rejection.

The claims are directed to a phenolic antioxidant-chromium complex. Claim 1 (and all claims dependent therefrom) contains the limitation that the phenolic antioxidant-chromium complex contains phenolic antioxidant that is in a purified tannin fraction of plant origin. Rowland does not disclose this and the Examiner failed to even address the missing limitation of the antioxidant that is in a purified tannin fraction. Because this limitation is not disclosed by Rowland, and is not addressed by the Examiner's rationale, the rejection fails to present a prima facie showing of anticipation.

Furthermore, Rowland never discloses a phenolic antioxidant-chromium complex that contains phenolic antioxidant of plant origin. The Examiner *attempted* (unsuccessfully) to show this limitation in Rowland by relying on the disclosure in Rowland explaining that Shilajit extract is *treated with herbs*. The Rowland disclosure states:

"The extracted Shilajit is then treated with a mixture of three herbs known as trifla, which includes amla (*emblica officinalis*), bahera (*terminalia chebula*), and haritaki (*terminalia belerica*), to remove possible contaminants. The purified Shilajit which is obtained is then dehydrated to remove moisture. The Shilajit

produced and refined by this method is almost totally sterile. Laboratory analysis reveals that it has a bacterial count of only 50 colonies per gram and a yeast-/fungus count of only 10 colonies per gram". (Col. 4, lines 45-50).

The Examiner's grounds for the rejection takes the approach that "treated with" means that the trifla was added to the Shilajit extract. However, this assumption is inconsistent with the rest of the wording of the paragraph. Rowland does not specifically state that the herb mixture is "added to" the Shilajit extract and this interpretation is inconsistent with the next sentence in the paragraph which states that "purified Shilajit" is obtained. If the trifla were added to the Shilajit extract, the trifla would be a contaminant of the Shilajit so they would not obtain "purified Shilajit." Thus, since Rowland obtains purified Shilajit, there can be no trifla added to the Shilajit. Therefore, the Examiner incorrectly characterized Rowland in stating: "Since Iron Shilajit is treated with *Emblica officinalis* it would inherently comprise phenolic antioxidant-chromium complex." (Off. Action, p. 3). (Applicant assumes the Examiner intended to write phenolic antioxidant-chromium complex of plant origin, as stated in the claims). The Examiner's statement does not satisfy the legal rules for inherent disclosure because the Examiner did not present a showing that Rowland's shilajit necessarily contains phenolic antioxidant of plant origin. In light of Rowland's disclosure that the Shilajit was "purified" after treatment with trifla, it appears impossible to assume that there was any *E. officinalis* added. Thus, since the reference failed to disclose phenolic antioxidant of plant origin, the rejection fails to present a prima facie showing of anticipation.

One can certainly envision other assumptions for "treating the Shilajit extract with trifla" that are more consistent with the context of the paragraph than the assumption the Examiner has chosen. For example, if "treating with trifla" meant that the trifla were used as a fumigant for the Shilajit extract, one could envision burning the trifla so as to produce smoke and directing the smoke to a container containing the Shilajit extract. If we assume that Rowland was explaining the treatment in terms of the smoke being a fumigant, it would be consistent with the disclosure that the Shilajit extract was rendered "almost totally sterile" of bacteria, yeast and fungus, yet there would be no trifla added to the extract, which would be consistent with the wording of the paragraph which explains that purified Shilajit was obtained. Applicant makes no assertion that this is what Rowland intended, since Rowland provides absolutely no indication of what was

intended. Applicant merely makes the point that as long as the argument is pivoting on assumptions, the better assumption to choose is the one that is most consistent with the information Rowland provides. Since the Examiner cannot show that trifla is necessarily added to the Shilajit, there can be no *prima facie* case based on inherent anticipation.

If the Examiner is relying on inherent anticipation, the law on inherency is strict; it requires the prior art must *necessarily* include the unstated limitation. *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Since Rowland is so indefinite and unclear as to the meaning of "treated with," and Applicant has provided a more consistent explanation (assumption), the Examiner has not established that Rowland necessarily disclosed a Shilajit preparation containing *emblica officinalis*.

On still other grounds, the rejection cannot stand because the prior art reference is non-enabling. Rowland does not make it clear what is done with the herbal mixture containing *emblica officinalis* in order to remove contaminants from the Shilajit extract. What is the "treatment"? How much of the herbs is used? What part of the herbal plant is used? Nor does Rowland disclose what the contaminants are that are removed. These contaminants might well be the antioxidant fraction, for all we can discern from this vague disclosure. Therefore, the reference is non-enabling and the rejection fails for yet another reason.

### 35 USC § 103

Claims 1-2, 9-11, 13 and 27 were rejected under 35 USC § 103(a) as being unpatentable over Janjua in view of Ghosal (U.S. Patent No. 6,124,268). Claims 6, 7, 22, 24-26, 30 and 34 were rejected as being unpatentable over Janjua in view of Ghosal (U.S. 6,124,268) and further in view of Riley (EP 0037144). Applicant traverses the rejections.

The Examiner relied on the theory of inherency to reject the claims. However, under this theory, the Examiner has the burden of providing a showing that the extrinsic evidence makes clear "that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); MPEP 2112, IV (Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient). Since the prior art did not disclose sufficient

information to show that the Examiner's assumption would *necessarily* be the case, reliance on the Janjua reference under inherency theory was improper. The Office Action stated that Janjua discloses that chromium is found in *Phyllanthus emblica* at a concentration of 2.5 µg/g. Janjua obtained these findings by heating the herb at 1200°C for 16 hours to obtain the ash. Measurements of atomic absorption of the ash were then obtained (Janjua, p. 104) to obtain the concentration of chromium. This is the full extent of the disclosure of methods in Janjua. There is no disclosure whether the chromium is compartmentalized in the same location as the antioxidant, let alone whether the chromium is actually complexed to the antioxidant. Without information about how these components are compartmentalized, the Examiner merely relied on assumption for the statement that: "*Phyllanthus emblica*, which naturally contains chromium, would inherently comprise an antioxidant-chromium complex." (Off. Act., p. 4). The Examiner has not provided a factual disclosure to show that chromium is found in the same compartment as is the antioxidant in the herb, so the Examiner has not shown that the *Phyllanthus emblica* necessarily would comprise antioxidant-chromium complex. For this reason, the reliance on inherency fails and there has been no prima facie showing of obviousness.

The Examiner's statement of motivation for the combination of Ghosal and Janjua also fails because it is based on the unproven assumption that *Phyllanthus emblica* contains chromium in the form of antioxidant-chromium complex. The Office Action states that it would have been obvious to purify the antioxidant-chromium complex from *Phyllanthus emblica* and to extract the antioxidant-chromium complex from *Phyllanthus emblica*. As argued above, the Examiner hasn't even presented evidence that there is an antioxidant-chromium complex in *Phyllanthus emblica*. Thus the Examiner failed to make the prima facie showing of obviousness for this reason, as well.

Claims 6, 7, and 26 were rejected under 35 USC 103(a) as unpatentable over Rowland as applied to claims 1-2, 9-11, 13-16, 22, 24-25, 27, 30, 33, 34, 36 and 38, above, and further in view of Riley. Applicant traverses the rejection. Since there was no prima facie showing of anticipation of these claims in view of Rowland, as argued above for anticipation, the Examiner has failed to make the showing necessary to support the prima facie case of obviousness, as well.

Furthermore, the present invention provides unexpected results in the form of showing substantially improved effect when an external source of chromium is mixed with a *Phyllanthus emblica* antioxidant fraction to form a phenolic antioxidant-chromium complex over the results obtained merely from the effect of providing *Phyllanthus emblica* alone. It is accepted law that: "when an applicant demonstrates *substantially* improved results, [as Soni did here,] and *states* that the results were *unexpected*, this should suffice to establish unexpected results *in the absence of* evidence to the contrary." *In re Soni*, 34 USPQ2d 1684, 1688 (Fed. Cir. 1995). At Example 4 of the Application (pages 29-30), an experiment is presented where mice were made diabetic by injection with streptozocine and then were treated with *Phyllanthus emblica* alone or with *Phyllanthus emblica* with exogenous chromium in the form of phenolic antioxidant-chromium complex. The results in Table 1 show that while *Phyllanthus emblica* extract at 10 mg/kg or 20 mg/kg prevents high serum glucose by 22 or 28% inhibition, respectively (N-1 and N-2), treatment with *Phyllanthus emblica* phenolic antioxidant-chromium complex produced a 58% inhibition of high serum glucose (N-3). Thus, the results provided in the Application provide a showing of unexpected results that weighs against the obviousness of the invention.

Applicant had also argued previously that secondary considerations in the form of long felt but unsolved need support the non-obviousness of the invention. Specifically, Applicant argued that it was recognized that chromium (III), as a dietary supplement, is converted to toxic chromium (VI) by spontaneous systematic oxidation and hence induces delayed toxicity and that it was recognized that safer alternatives were needed. The complete argument is on the record.

#### **Obviousness-Type Double Patenting**

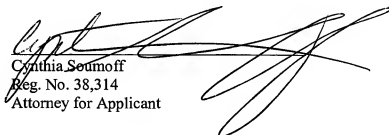
Claims 1, 14, 15, 22, 33 and 36 were rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claim 1 and 2 of Ghosal (US 6,440,436) and claim 1 and 7 of Ghosal (US 6,869,612).

Without acquiescing to the correctness of this rejection, in order to advance prosecution, Applicant will file a Terminal Disclaimer at such time as agreement is reached that the claims are otherwise in condition for allowance, if at that time, the form of the claims has not been appreciably amended so as to remove the claims from the obviousness-type double patenting rejection.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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